



IFW

141-424

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE
PATENT OPERATION

In re Application of:

Kositprapa et al.

Serial No.: 10/664,803

Group Art Unit: --

Filed: September 19, 2003

Examiner: --

**For: NOVEL PHARMACEUTICAL FORMULATION CONTAINING A BIGUANIDE
AND A THIAZOLIDINEDIONE DERIVATIVE**

New York, NY 10036
December 22, 2003

Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

INFORMATION DISCLOSURE STATEMENT

Sir:

The following statement of relevance is submitted with the accompanying
Form PTO/SB/08A.

Document
Designation

Relevance

AA
U.S.P. 3,174,901

Relates to a process for the oral treatment of diabetes.

AB
U.S.P. 3,960,949

Relates to 1,2-biguanides.

AC
U.S.P. 4,166,800

Relates to a process for preparation of microspheres.

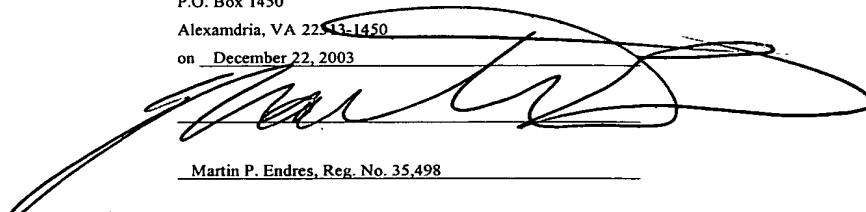
I hereby certify that this correspondence is being deposited with the
United States Postal Service as first class mail in an envelope
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Commissioner for Patents

P.O. Box 1450

Alexandria, VA 22313-1450

on December 22, 2003


Martin P. Endres, Reg. No. 35,498

| <u>Document Designation</u> | <u>Relevance</u> |
|---------------------------------|---|
| AD U.S.P. 4,389,330 | Relates to a microencapsulation process. |
| AE U.S.P. 4,687,777 | Relates to a thiazolidinedione derivative, useful as an antidiabetic agent. |
| AF U.S.P. 4,839,177 | Relates to a system for the controlled-rate release of active substances. |
| AG U.S.P. 4,891,223 | Relates to a controlled release delivery coating formulation for bioactive substances. |
| AH U.S.P. 4,968,507 | Relates to a controlled porosity osmotic pump. |
| AI U.S.P. 5,294,770 | Relates to a laser tablet treatment system. |
| AJ U.S.P. 5,356,913 | Relates to the use of insulin sensitizing agents to treat hypertension. |
| AK U.S.P. 5,376,771 | Relates to a high speed process for preparing orifices in pharmaceutical dosage forms. |
| AL U.S.P. 5,478,852 | Relates to a use of thiazolidinedione derivatives and related antihyperglycemic agents in the treatment of impaired glucose tolerance in order to prevent or delay the onset of noninsulin-dependent diabetes mellitus. |
| AM U.S.P. 5,602,133 | Relates to a use of thiazolidinedione derivatives and related antihyperglycemic agents in the treatment of disease states at risk for progressing to noninsulin-dependent diabetes mellitus. |
| AN U.S.P. 5,658,474 | Relates to a method and apparatus for forming dispenser delivery ports. |
| AO U.S.P. 5,681,584 | Relates to a controlled release drug delivery device. |
| AP U.S.P. 5,698,220 | Relates to an asymmetric membrane for use in drug delivery devices. |
| AQ U.S.P. 5,719,188 | Relates to the use of insulin sensitizing agents to treat hypertension. |
| AR U.S.P. 5,859,037 | Relates to sulfonylurea-glitazone combinations for diabetes. |

| | |
|------------------------|--|
| AS U.S.P. 5,916,584 | Relates to a controlled release container with a core and an outer shell. |
| AT U.S.P. 5,952,356 | Relates to a pharmaceutical composition. |
| AU U.S.P. 5,955,106 | Relates to a pharmaceutical preparation containing metformin and a process for producing it. |
| AV U.S.P. 6,011,049 | Relates to drug combinations for treating diabetes. |
| AW U.S.P. 6,031,004 | Relates to salts of metformin. |
| AX U.S.P. 6,099,859 | Relates to a controlled release oral tablet having a unitary core. |
| AY U.S.P. 6,153,632 | Relates to a method and composition for the treatment of diabetes. |
| AZ U.S.P. 6,191,162 | Relates to a method of reducing serum glucose levels. |
| BA U.S.P. 6,248,363 | Relates to a solid carrier for improved delivery of active ingredients in pharmaceutical compositions. |
| BB U.S.P. 6,291,495 | Relates to a method and composition for the treatment of diabetes. |
| BC U.S.P. 6,296,874 | Relates to a core formulation comprising troglitazone and a biguanide. |
| BD U.S.P. 6,329,403 | Relates to a pharmaceutical composition for the treatment of diabetes. |
| BE U.S.P. 6,383,471 | Relates to a composition and method for improved delivery of ionizable hydrophobic therapeutic agents. |
| BF U.S.P. 6,403,121 | Relates to a core formulation. |
| BG US 2002/0071866 | Relates to a dosage form having a barrier layer to laser ablation. |
| BH U.S.P. 6,451,342 | Relates to a core formulation comprised of troglitazone and a biguanide. |

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|------------------------|---|
| BI U.S.P. 6,475,521 | Relates to a biphasic controlled release delivery system for high solubility pharmaceuticals. |
| BJ U.S.P. 6,524,621 | Relates to a core formulation. |
| BK US 2003/0113371 | Relates to a composition and method for maintaining blood glucose level by employing a hydrophilic matrix based oral controlled release antidiabetic composition. |
| BL US 2003/0118647 | Relates to an extended release tablet of metformin. |
| BM US 2003/0118649 | Relates to a drug delivery device. |
| BN U.S.P. 6,599,284 | Relates to an osmotic device having a preformed passageway that increases in size. |
| CA WO 96/09823 | Relates to a hypoglycemic agent from cryptolepis. |
| CB WO 98/11879 | Relates to a gastric-retentive, oral drug dosage form for the controlled-release of sparingly soluble drugs and insoluble matter. |
| CC WO 98/55107 | Relates to a gastric-retentive oral drug dosage form for controlled release of highly soluble drugs. |
| CD WO 99/47128 | Relates to a biphasic controlled release delivery system for high solubility pharmaceuticals. |
| CE WO 99/55320 | Relates to an oral formulation comprising a biguanide and an organic acid. |
| CF WO 00/28989 | Relates to a pharmaceutical composition for modified release of an insulin sensitizer and another antidiabetic agent. |
| CG WO 00/72827 | Relates to porous drug matrices and methods of manufacture thereof. |
| CH WO 01/35940 | Relates to a composition comprising a thiazolidinedione metformin hydrochloride. |
| CI WO 01/35941 | Relates to a composition comprising a thiazolidinedione metformin hydrochloride. |
| CJ WO 01/82875 | Relates to a core formulation comprising pioglitazone and a biguanide. |

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| CK WO 02/28181 | Relates to a sustained release pharmaceutical composition containing metformin and a method for its production. |
| CL WO 03/004009 | Relates to a pharmaceutical composition. |
| CM WO 03/35029 | Relates to a formulation of an erodible, gastric retentive oral dosage form using in vitro disintegration test data. |
| CN WO 03/047529 | Relates to an extended release pharmaceutical tablet of metformin. |
| CO EP 0 169 105 | Relates to a controlled porosity osmotic pump. |
| CP EP 0 283 369 | Relates to metformin dosage formulation. |
| CQ EP 0 381 181 | Relates to a system for the controlled release of active agents and a process for its preparation. |
| CR EP 0 749 751 | Relates to a pharmaceutical composition for use in treatment of diabetes. |
| CS EP 0 753 298 | Relates to a synergistic combination comprising an insulin sensitizer and a HMG-CoA reductase inhibitor for treating arteriosclerosis. |
| CT EP 0 781 129 | Relates to a pharmaceutical preparation containing metformin and a process for producing it. |
| DA P. Karttunen et al. International Journal of Clinical Pharmacology, Therapy and Toxicology, "The pharmacokinetics of metformin: a comparison of the properties of a rapid-release and a sustained-release preparation" Vol. 21 No. 1 – 1983, pp. 31-36. | Relates to a sustained release metformin dosage form. |
| DB P.J. Pentikainen International Journal of Clinical Pharmacology, Therapy and Toxicology, "Bioavailability of metformin. Comparison of solution, rapidly dissolving tablet, and three sustained release products" Vol. 24 No. 4 – 1986, pp. 213-220 | Relates to a sustained release metformin dosage form. |

DC Relates to a sustained release metformin dosage form.
Finnish Monograph of the Diformin®
Retard table
with English translation

DD Relates to metformin dosage form.
O.J. Lucis, MD, Ph. D., MSC
Canada Medical Association J.
Pharmacologic Update
“The status of metformin
in Canada” Vol. 128
January 1, 1983 pgs. 24-26

DE Relates to pioglitazone.
G. Belcher and D.R. Matthews
Experiment and Clinical
Endocrinology & Diabetes
“Safety and tolerability
of pioglitazone” Suppl 2
(2000) pgs. 267-273

DF Relates to a pioglitazone and metformin dosage forms.
Daniel Einhorn, MD et al.
Clinical Therapeutics
“Pioglitazone Hydrochloride in
Combination with Metformin in
the Treatment of Type 2 Diabetes
Mellitus: A Randomized, Placebo-
Controlled Study”,
Vol. 22 No. 12, 2000 pgs. 1395-1413

DG Relate to pioglitazone.
National Institute for Clinical Excellence
Technology Appraisal Guidance – No. 21
“Guidance on the Use of Pioglitazone for
Type 2 Diabetes Mellitus”
March 2001, pgs. 1-13

DH Relates to pioglitazone.
The Pharmaceutical Journal
Vol. 265, No. 7122, p. 710
November 11, 2000 Clinical
(abstract only)

DI Relates to a metformin extended-release tablet.
Product Labeling for
Glucophage® XR (July 2002)

DJ
ADA Professional Section
Member Supplement
047 and 0503-506 (Poster)
p. A110; A117

Relates to combination therapy with pioglitazone and insulin in patients with Type 2 diabetes.

DK
Website
www.findarticles.com
Clinician Reviews
"Insulin-Sensitizing Diabetes Agent"
September 1999

Relates to an insulin-sensitizing diabetes agent.

DL
ACTOS® product label
Physician's Desk Reference
55TH Edition, pp. 3171-3175

Relates to pioglitazone dosage formulation.

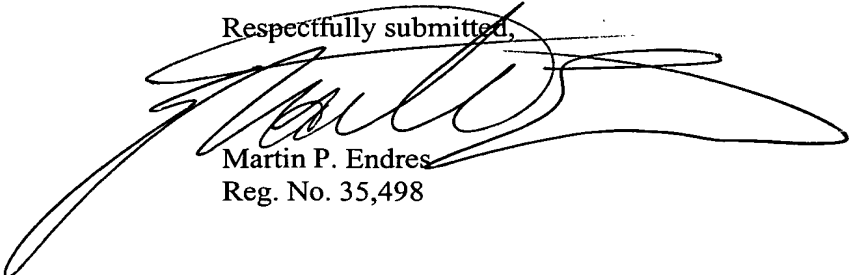
DM
Rote Liste No. 11081 the Medicament
Mediabet of MEDICE, Chem.-
Pharm. Fabrik Pütter GmbH & Co.
KG, Kuhloweg 37-39 Iserlohn/Germany,
Editio Cantor Verlag für Medizin und
Naturwissenschaften GmbH, 1993.

Relates to Mediabet which is a tablet containing metformin.

Full text copies of the prior art are enclosed herewith. It is respectfully requested that this art be considered by the Examiner in the above-entitled application and made of record therein.

Pursuant to 37 C.F.R. §1.97 it is believed that no fee is required for consideration of this Information Disclosure Statement. If a fee is required, the Commissioner is hereby authorized to charge Deposit Account No. 08-1540.

Respectfully submitted,



Martin P. Endres
Reg. No. 35,498

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Substitute for form 1449A/PTO

INFORMATION DISCLOSURE STATEMENT BY APPLICANT

(use as many sheets as necessary)

Sheet 1 of 5

Complete if Known

| | |
|-------------------------------|---------------------|
| Application Number | 10/664,803 |
| Filing Date | September 19, 2003 |
| First Named Inventor | Unchalee Kositprapa |
| Art Unit | |
| Examiner Name | |
| Attorney Docket Number | 141-424 |

U.S. PATENT DOCUMENTS

| Examiner Initials* | Cite No. 1 | Document Number | Publication Date MM-DD-YYYY | Name of Patentee or Applicant of Cited Document | Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear |
|-----------------------|---------------|--|--------------------------------|--|---|
| | | Number - Kind Code ² (If known) | | | |
| | AA | us-3,174,901 | 03-23-1965 | Sterne | |
| | AB | us-3,960,949 | 06-01-1976 | Ahrens et al. | |
| | AC | us-4,166,800 | 09-04-1979 | Fong | |
| | AD | us-4,389,330 | 06-21-1983 | Tice et al. | |
| | AE | us-4,687,777 | 08-18-1987 | Meguro et al. | |
| | AF | us-4,839,177 | 06-13-1989 | Colombo et al. | |
| | AG | us-4,891,223 | 01-02-1990 | Ambegaonkar et al. | |
| | AH | us-4,968,507 | 11-06-1990 | Zentner et al. | |
| | AI | us-5,294,770 | 03-15-1994 | Riddle et al. | |
| | AJ | us-5,356,913 | 10-18-1994 | Colca | |
| | AK | us-5,376,771 | 12-27-1994 | Roy | |
| | AL | us-5,478,852 | 12-26-1995 | Olefsky et al. | |
| | AM | us-5,602,133 | 02-11-1997 | Antonucci et al. | |
| | AN | us-5,658,474 | 08-19-1997 | Geerke | |
| | AO | us-5,681,584 | 10-28-1997 | Savastano et al. | |
| | AP | us-5,698,220 | 12-16-1997 | Cardinal et al. | |
| | AQ | us-5,719,188 | 02-17-1998 | Colca | |
| | AR | us-5,859,037 | 01-12-1999 | Whitcomb | |
| | AS | us-5,916,584 | 06-29-1999 | O'Donoghue et al. | |
| | AT | us-5,952,356 | 09-14-1999 | Ikeda et al. | |

FOREIGN PATENT DOCUMENTS

[illegible]

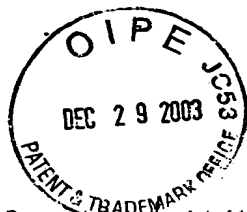
Examiner
Signature

Date Considered

*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

¹ Applicant's unique citation designation number (optional). ² See Kinds Codes of USPTO Patent Documents at www.uspto.gov or MPEP 901.04. ³ Enter Office that issued the document, by the two-letter code (WIPO Standard ST.3). ⁴ For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. ⁵ Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST. 16 if possible. ⁶ Applicant is to place a check mark here if English language Translation is attached.

Burden Hour Statement: This form is estimated to take 2.0 hours to complete. Time will vary depending upon the needs of the individual case. Any comments on the amount of time you are required to complete this form should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, Washington, DC 20231. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Assistant Commissioner for Patents, Washington, DC 20231.



Approved for use through 10/31/2002. OMB 0651-0031
U.S. Patent and Trademark Office: U.S. DEPARTMENT OF COMMERCE

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| Substitute for form 1449A/PTO INFORMATION DISCLOSURE STATEMENT BY APPLICANT (use as many sheets as necessary) Sheet <u>2</u> of <u>5</u> | | Complete if Known | |
| | | Application Number | 10/664,803 |
| | | Filing Date | September 19, 2003 |
| | | First Named Inventor | Unchalee Kositprapa |
| | | Art Unit | |
| | | Examiner Name | |
| | | Attorney Docket Number | 141-424 |

| U.S. PATENT DOCUMENTS | | | | | |
|-----------------------------------|--------------------------|--|--------------------------------|--|---|
| Examiner Initials ⁷ | Cite No. ¹ | Document Number | Publication Date MM-DD-YYYY | Name of Patentee or Applicant of Cited Document | Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear |
| | | Number - Kind Code ² (if known) | | | |
| | AU | US- 5,955,106 | 09-21-1999 | Moeckel et al. | |
| | AV | us-6,011,049 | 01-04-2000 | Whitcomb | |
| | AW | us-6,031,004 | 02-29-2000 | Timmins et al. | |
| | AX | us-6,099,859 | 08-08-2000 | Cheng et al. | |
| | AY | us-6,153,632 | 11-28-2000 | Rieveley | |
| | AZ | us- 6,191,162 | 02-20-2001 | Byrd et al. | |
| | BA | us- 6,248,363 | 06-19-2001 | Patel et al. | |
| | BB | us- 6,291,495 | 09-18-2001 | Rieveley | |
| | BC | us- 6,296,874 | 10-02-2001 | Cutie et al. | |
| | BD | us- 6,329,403 | 12-11-2001 | Odaka et al. | |
| | BE | us- 6,383,471 | 05-07-2002 | Chen et al. | |
| | BF | us-6,403,121 | 06-11-2002 | Adjei et al. | |
| | BG | us- 2002/0071866 | 06-13-2002 | Geerke | |
| | BH | us-6,451,342 | 09-17-2002 | Adjei et al. | |
| | BI | us-6,475,521 | 11-05-2002 | Timmins et al. | |
| | BJ | us- 6,524,621 | 02-25-2003 | Adjei et al. | |
| | BK | us-2003/0113371 | 06-19-2003 | Dhawan et al. | |
| | BL | us- 2003/0118647 | 06-26-2003 | Seth | |
| | BM | us- 2003/0118649 | 06-26-2003 | Gao et al. | |
| | BN | us- 6,599,284 | 07-29-2003 | Faur | |

| FOREIGN PATENT DOCUMENTS | | | | | | |
|--------------------------------|-----------------------|---|-----------------------------|---|---|----------------|
| Examiner Initials ⁷ | Cite No. ¹ | Foreign Patent Document | Publication Date MM-DD-YYYY | Name of Patentee or Applicant of Cited Document | Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear | T ⁶ |
| | | Country Code ³ - Number ⁴ - Kind Code ⁵ (if known) | | | | |
| | CA | WO 96/09823 ✓ | 04-04-1996 | Luo et al. | | |
| | CB | WO 98/11879 ✓ | 03-26-1998 | Shell et al. | | |
| | CC | WO 98/55107 ✓ | 12-10-1998 | Shell et al. | | |
| | CD | WO 99/47128 ✓ | 09-23-1999 | Timmins et al. | | |
| | CE | WO 99/55320 ✓ | 11-04-1999 | Nishii et al. | | |
| | CF | WO 00/28989 ✓ | 05-25-2000 | Lewis et al. | | |
| | CG | WO 00/72827 ✓ | 12-07-2000 | Straub et al. | | |
| | CH | WO 01/35940 | 05-25-2001 | Lewis et al. | | |
| | CI | WO 01/35941 | 05-25-2001 | Lilliot et al. | | |
| | CJ | WO 01/82875 | 11-08-2001 | Cutie et al. | | |

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| Examiner Signature | Date Considered |
|-----------------------|--------------------|

*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

¹ Applicant's unique citation designation number (optional). ² See Kinds Codes of USPTO Patent Documents at www.uspto.gov or MPEP 901.04. ³ Enter Office that issued the document, by the two-letter code (WIPO Standard ST.3). ⁴ For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. ⁵ Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST. 16 if possible. ⁶ Applicant is to place a check mark here if English language Translation is attached.

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PTO/SB/08B (10-01)
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U.S. Patent and Trademark Office: U.S. DEPARTMENT OF COMMERCE

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| Substitute for form 1449B/PTO | | Completion if Known | |
| INFORMATION DISCLOSURE STATEMENT BY APPLICANT (use as many sheets as necessary) | | Application Number | 10/664,803 |
| | | Filing Date | September 19, 2003 |
| | | First Named Inventor | Unchalee Kositprapa |
| | | Group Art Unit | |
| | | Examiner Name | |
| Sheet 4 of 5 | Attorney Docket Number | 141-424 | |

| OTHER PRIOR ART -- NON PATENT LITERATURE DOCUMENTS | | | |
|---|-----------------------|--|----------------|
| Examiner Initials ² | Cite No. ¹ | Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published | T ² |
| | DA | P. Karttunen et al., International Journal of Clinical Pharmacology, Therapy and Toxicology, "The pharmacokinetics of metformin: a comparison of the properties of a rapid release and a sustained-release preparation" Vol. 21, No. 1 - 1983, pp. 31-36. | |
| | DB | P.J. Pentikainen, International Journal of Clinical Pharmacology, Therapy and Toxicology, "Bioavailability of metformin. Comparison of solution, rapidly dissolving-tablet, and three sustained-release products", Vol. 24, No. 4 - 1986, pp. 213-220. | |
| | DC | Finnish Monograph of the Diformin®, Retard tablet, with English translation | |
| | DD | O.J. Lucis, MD, Ph.D., MSC, Canada Medical Association J. Pharmacologic Update "The status of metformin in Canada" Vol. 128, January 1, 1983, pgs. 24-26. | |
| | DE | G. Belcher and D.R. Matthews Experiment and Clinical Endocrinology & Diabetes, "Safety and tolerability of pioglitazone" Suppl. 2 (2000) pgs. 267-273. | |
| | DF | Daniel Einhorn, MD et al., Clinical Therapeutics "Pioglitazone Hydrochloride in Combination with Metformin in the Treatment of Type 2 Diabetes Mellitus: A Randomized, Placebo-Controlled Study", Vol. 22, No. 12, 2000 pgs. 1395-1413. | |
| | DG | National Institute for Clinical Excellence Technology Appraisal Guidance - No. 21, "Guidance on the Use of Pioglitazone for Type 2 Diabetes Mellitus" March 2001, pgs. 1-13. | |
| | DH | The Pharmaceutical Journal, Vol. 265, No. 7122, p. 710 November 11, 2000 Clinical (abstract only). | |

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|---------------------------|--|------------------------|--|
| Examiner Signature | | Date Considered | |
|---------------------------|--|------------------------|--|

*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

¹ Applicant's unique citation designation number (optional). ² Applicant is to place a check mark here if English language Translation is attached.

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| Substitute for form 1449B/PTO | | Complete if Known | |
| INFORMATION DISCLOSURE STATEMENT BY APPLICANT (use as many sheets as necessary) | | Application Number | 10/664,803 |
| | | Filing Date | September 19, 2003 |
| | | First Named Inventor | Unchalee Kositprapa |
| | | Group Art Unit | |
| | | Examiner Name | |
| Sheet 5 | of 5 | Attorney Docket Number | 141-424 |

| OTHER PRIOR ART -- NON PATENT LITERATURE DOCUMENTS | | | |
|---|---------------------------------|--|----------------------|
| Examiner Initials* | Cite No.¹ | Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published. | T² |
| | DI | Product Labeling for Glucophage® XR (July 2002). | |
| | DJ | ADA Professional Section Member Supplement 047 and 0503-506 (Poster) p. A110; A117 | |
| | DK | Website www.findarticles.com, Clinician Reviews, "Insulin-Sensitizing Diabetes Agent" September 1999. | |
| | DL | ACTOS® product label, Physician's Desk Reference, 55th Edition, pp. 3171-3175 | |
| | DM | Rote Liste No. 11081 the Medicament Mediabet of MEDICE, Chem.-Pharm. Fabrik Pütter GmbH & Co. KG, Kuhlweg 37-39 Iserlohn/Germany, Editio Cantor Verlag für Medizin und Naturwissenschaften GmbH, 1993. | |
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| Examiner Signature | | Date Considered | |
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